

CLAIMS

What is claimed is:

1. A system for the creation or modification of an orthopedic joint within a mammalian body, the system comprising one or more partially or fully preformed polymeric components, adapted to be inserted and positioned at a joint site to provide an implant having at least one major surface in apposition to supporting bone, and at least a second major surface in apposition to opposing bone,
 - wherein the implant is a knee implant and provides a first major surface adapted to be positioned upon and congruent with the tibial surface of the knee, and a second major surface adapted to be positioned against the femoral condyle of the knee,
 - and wherein the second major surface is provided with a femoral glide path to facilitate its performance *in situ*, the glide path being in the form of a generally central depression,
 - the implant further comprising one or more tibial projections adapted to extend distally over the rim of the tibial plateau in order to improve fixation *in situ*.
2. A system according to claim 1 wherein the polymeric components are provided in the form of a single preformed component comprising a biomaterial partially or completely cured in an *ex vivo* mold.
3. A system according to claim 1 wherein the tibial projection(s) are adapted to catch the posterior portion of the tibial plateau by extending over the rim of the tibial plateau distally, and the preformed component has dimensions on the order of between about 30 to about 60 mm in the anterior-posterior dimension, between about 20 mm to about 40 mm in the medial-lateral dimension, and a maximum thickness, at the posterior lip, of between about 8 mm and about 20 mm, or about 3mm to about 10 mm greater than the thickness of the implant at the center.
4. A system according to claim 1 wherein the implant further comprises at least one ancillary component integrated into, and partially extending from, the implant to provide anterior fixation.
5. A system according to claim 4 wherein the ancillary component comprises one or more protrusions adapted to be attached to either soft tissue and/or bone at the joint site to improve fixation.

6. A system according to claim 5 wherein the protrusions are adapted to be integrated into the preformed component during an *ex vivo* molding process.

7. A system according to claim 6 wherein the protrusions are comprised of sutures and/or fibrous biomaterials integrally formed with the preformed component itself.

5 8. A system according to claim 1 further comprising one or more separate components for securing the implant to the joint site, selected from the group consisting of adhesives, sutures, pins, staples, screws, and combinations thereof.

10 9. A system according to claim 2 wherein a plurality of preformed components are provided in a corresponding plurality or range of styles and sizes for selection and use in the surgical field.

10. A system according to claim 1 wherein one or more of the polymeric components comprise a polyurethane.

11. A system according to claim 10 wherein the polyurethane is prepared from polyisocyanate(s), short and long chain polyols, and optionally including one or more 15 ingredients selected from the group hydrophobic additive(s), tin and/or amine catalyst(s), and antioxidant(s).

12. A system according to claim 10 wherein the polyurethane comprises aromatic polyisocyanates, PTMO's, and short chain diols.

13. A system according to claim 11 wherein the hydrophobic additive 20 comprises hydroxyl-terminated polybutadiene, and the tin and/or amine catalyst(s) are adapted to promote the isocyanate - hydroxyl reaction preferentially and are selected from the group consisting of UL22, Cotin 222, 1,4-diazabicyclo[2.2.2]octane (dabco), and dibutyltin dilaurate (DBTDL), and combinations thereof.

14. A system according to claim 10 wherein the polyurethane comprises an 25 isocyanate selected from the group consisting of aromatic, aliphatic and arylalkyl diisocyanates, and combinations thereof.

15. A system according to claim 14 wherein the isocyanate is selected from the 30 group consisting of toluene diisocyanates, naphthalene diisocyanates, phenylene diisocyanates, xylylene diisocyanates, diphenylmethane diisocyanates, cyclohexane diisocyanates, cyclohexyl-bis methylene diisocyanates, isophorone diisocyanates and hexamethylene diisocyanate

16. A system according to claim 1, wherein the polymeric component comprises one or more surfaces having attached thereto a biologically active agent selected from the group cytokines, growth factors, autologous growth factors, hydroxyapatite, collagen, and combinations thereof.

5 17. A system according to claim 1 wherein the surface of the polymeric component is provided or modified with reactive groups to promote tissue adhesion.

18. A system according to claim 17 wherein the reactive groups are provided by the polymers used to fabricate the polymeric component, and are selected from amines, hydroxyl groups, or other reactive or hydrogen bonding functionalities.

10 19. A system according to claim 1 wherein the glide path is in the form of a generally central oval depression about 0.5 mm to about 5mm deep at its lowest point and about 20 mm to about 50 mm in length by 10 mm to 30 mm in width.

15 20. A system according to claim 2 wherein the component is preformed in a mold having an anterior cup edge that is substantially perpendicular to the plane of the cup itself, and a posterior mesial edge that is tapered to accommodate the corresponding shape of the tibial spine.

21. A system according to claim 20 wherein the mold is adapted to permit control of sizing, conformance to the joint site, implant thickness and angular correction.

20 22. A system according to claim 1 further comprising a patella-femoral joint form suitable adapted to be formed to, and held against, the femoral bone surface, in order to permit the delivery of curable biopolymer between the form and the bone.

25 23. A system according to claim 1 wherein the polymeric components are provided in the form of a single preformed component comprising a polyurethane partially or completely cured in an *ex vivo* mold, and wherein the implant that comprises the preformed component further comprises at least one ancillary component integrated into, and partially extending from, the implant to provide anterior fixation.

24. A system according to claim 23 wherein the polyurethane comprises an isocyanate selected from the group consisting of aromatic, aliphatic and arylalkyl diisocyanates, and combinations thereof.

30 25. A system according to claim 24 wherein the isocyanate is selected from the group consisting of toluene diisocyanates, naphthalene diisocyanates, phenylene diisocyanates, xylylene diisocyanates, diphenylmethane diisocyanates, cyclohexane

diisocyanates, cyclohexyl-bis methylene diisocyanates, isophorone diisocyanates and hexamethylene diisocyanate

26. A system according to claim 23, wherein the polymeric component comprises one or more surfaces having attached thereto a biologically active agent
5 selected from the group cytokines, growth factors, autologous growth factors, hydroxyapatite, collagen, and combinations thereof.

27. A system according to claim 3 wherein the surface of the polymeric component is provided or modified with reactive groups to promote tissue adhesion.

28. A system according to claim 3 wherein the glide path is in the form of a
10 generally central oval depression about 0.5 mm to about 5mm deep at its lowest point and about 20 mm to about 50 mm in length by 10 mm to 30 mm in width.

29. A system according to claim 15 wherein the glide path is in the form of a generally central oval depression about 0.5 mm to about 5mm deep at its lowest point and about 20 mm to about 50 mm in length by 10 mm to 30 mm in width.

15 30. A system according to claim 23 wherein the biomaterial comprises a polyurethane and the glide path is in the form of a generally central oval depression about 0.5 mm to about 5mm deep at its lowest point and about 20 mm to about 50 mm in length by 10 mm to 30 mm in width.

20 31. A system for the creation or modification of the wear surface of an orthopedic joint within a mammalian body, the system comprising one or more partially or fully preformed polymeric components, adapted to be inserted and positioned at a joint site to provide an implant having at least one major surface in apposition to supporting bone, and at least a second major surface in apposition to opposing bone.

25 32. A system according to claim 31 wherein one or more of the polymeric components are formed at the time of use, by the use of a curable polymer system adapted to be at least partially cured and partially formed by *ex vivo* molding in order to provide an implantable component adapted to be inserted and positioned *in vivo*, under conditions suitable to permit the implanted component to become finally formed upon reestablishing the natural joint space and in conformance with the opposing bone surfaces of the
30 orthopedic joint site.

33. A system according to claim 31 wherein the polymeric components comprise a plurality of packaged, preformed components adapted to be assembled at the

orthopedic joint site in a minimally invasive fashion to provide a final prosthesis having surfaces in conformance with the opposing bone surfaces of the orthopedic joint site.

34. A system according to claim 31 further comprising an *ex vivo* mold having a molding surface adapted to provide a roughened, patterned, and/or contoured surface to 5 the partially preformed component, in a manner sufficient to provide improved retention and fit of the component at the joint site.

35. A system according to claim 34 wherein the mold further provides ancillary means adapted to be incorporated into the preformed component for securing the component once formed in the joint site.

10 36. A system according to claim 35 wherein the ancillary means comprise one or more protrusions adapted to be attached to either soft tissue and/or bone at the joint site to improve fixation.

15 37. A system according to claim 34 wherein the contoured surface comprises a contour having one or more protrusions, integral with the preformed component, and formed during the *ex vivo* molding process.

38. A system according to claim 36 wherein the protrusions are adapted to be integrated into the preformed component during the *ex vivo* molding process.

39. A system according to claim 37 wherein the protrusions are comprised of sutures and/or fibrous biomaterials integrally formed with the component itself.

20 40. A system according to claim 34 further comprising separate means, not associated with the mold itself, for securing the component to the joint site, selected from the group consisting of adhesives, sutures, pins, staples, screws, and combinations thereof.

41. A system according to claim 31 wherein the one or more preformed 25 polymeric component(s) are adapted to be inserted into a joint in a minimally invasive fashion.

42. A system according to claim 32 in which the preformed component(s) and/or corresponding mold(s) are provided in a plurality or range of styles and sizes for selection and use in the surgical field.

30 43. A system according to claim 31 wherein the implant is adapted for use on the tibial surface of the knee, and provides portions adapted to conform to the shape of the femoral condyle and corresponding medial tibial plateau, lateral tibial plateau, or both.

44. A system according to claim 31 wherein the polymeric component is fabricated from a material selected from the group consisting of polyurethanes, polyureas, hydrogels, polysiloxanes, polyacrylates, and epoxies, and combinations thereof.

45. A system according to claim 44 wherein the polymeric component
5 comprises a polyurethane.